SIKKIM

GOVERNMENT GAZETTE

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GOVERNMENT OF SIKKIM
DEPARTMENT OF HEALTH CARE, HUMAN SERVICE AND FAMILY WELFARE

NOTIFICATION

No.07/HC, HS & F.W Dated: 9. 02. 2007.

SIKKIM ANTI DRUGS RULES, 2007

In exercise of the powers conferred by section 42 of the Sikkim Anti Drugs Act, 2006 (2 0f 2006), the State Government hereby makes the following rules, namely:

CHAPTER I
PRELIMINARY

Short title, extent and commencement.

1. (1) These rules may be called the Sikkim Anti Drugs Rules, 2006.
(2) It extends to the whole of Sikkim.
(3) It shall come into force at once.

Definitions.

2. In these rules, unless the context otherwise requires-
(a) "Act" means the Sikkim Anti Drugs Act, 2006;
(b) "addict" means a person who has dependence on any drug having abuse potential and consumes the said drug;
(c) "authorized person" means a person who has been given permission or authority by the Programme Officer or the issuing authority to deal in controlled substances;
(d) "controlled substance" means any substance declared by the Government by notification under clause (iii) of section 2 of the Act;
(e) "Government" means the Government of Sikkim;
(f) "issuing authority" means the Programme Officer or any other officer who may be authorized in this behalf by the Government for issuing a license or a permit;
(g) "license" means a license issued under these rules;
(h) "licensed dealers" means the traders or transporters who have the valid drug license and/or trade license to deal in controlled substances;
(i) "Programme Officer" means an officer appointed by the Government by notification under sub-section (1) of section 4 of the Act.

CHAPTER II
POWERS OF OFFICERS

Delegation of powers.

3. Subject to such directions as may be given by the Government, the Programme Officer appointed by the Government under sub-section (1) of section 4 of the Act, may authorize any officer subordinate to him, to exercise all or any of the powers under these rules.

Programme Officer and other officers to exercise powers of their subordinates.

4. The Programme Officer and such other officer as may be appointed by the Government under sub-section (1) of section 4 of the Act may perform all or any of the functions, or exercise any of the powers, assigned under these rules to the officers subordinate to them.

CHAPTER III
MANUFACTURE, SALE AND TRANSPORT OF CONTROLLED SUBSTANCES

Manufacture of controlled substances.

5. (1) The manufacture of controlled substances notified under clause (iii) of section 2 of the Act is prohibited save under and in accordance with the conditions of a license granted by the Programme Officer or such other officer as may be authorized by the Government, in Form No. I appended to these rules:
Provided that if the controlled substance being manufactured are medicinal preparations, a drug manufacturing license shall be obtained from the Licensing Authority notified under the Drugs and Cosmetics Act, 1940.
(2) A fee of rupees one thousand five hundred shall be payable in advance to the Government for each license issued under these rules or for renewal thereof. The license shall be renewed biannually.

Application for license.

6. Every application for license or for renewal thereof under rule 5 shall be made in Form No II appended to these rules.

Manufacture only from materials lawfully possessed.

7. The licensee shall not manufacture the drug save from the materials which he is lawfully entitled to possess.

Security arrangements.

8. The licensee shall ensure all necessary security arrangements in the manufacturing premises as may be specified by the issuing authority.

Maintenance of accounts and submission of returns.

9. The licensee shall maintain true accounts of all transactions including the account of materials used for the manufacture of controlled substances, the quantities manufactured, sold or otherwise disposed of and furnish returns in Form No. III appended to these rules.

Suspension and revocation of license.

10. (1) Without prejudice to any action that may be taken under the provisions of the Act, the issuing authority may suspend or cancel a license,
(i) if the license is transferred or sublet without the prior approval of the issuing authority;
(ii) in the event of any breach of any condition of the license; or

(iii) if the licensee is convicted of any offence under the Act or any other law relating to controlled substances for the time being in force in the State.

(2) No order shall be passed under sub-rule (1) unless the licensee has been given a reasonable opportunity showing cause against the said order or is heard in person, if he so desires.

Disposal of stocks of drugs on cancellation of license, etc.

11. Such stocks of drugs as may be in possession of the licensee, on the expiry or cancellation or surrender of his license, shall be disposed by the Programme Officer and the sales receipt of the same shall be credited to the Fund.

Sale of controlled substances.

12. The sale of controlled substances notified under clause (iii) of section 2 of the Act is prohibited save under and in accordance with the conditions of a license granted under (a) the Drugs and Cosmetics Act, 1940 for the sale of drugs, and (b) the Sikkim (Repeal and Miscellaneous Provisions) Act, 1985 for non drug substances.

Maintenance of accounts.

13. The licensee shall maintain in Form IV appended to these rules, accounts of all transactions of controlled substances, including the purchase and sale vouchers, the names of the prescribing registered medical practitioners or hospitals in case medicinal preparations, and furnish returns in Form V appended to these rules.

Inspections of stocks, etc.

14. (1) The stocks of controlled substances and all accounts of records and transactions relating thereto, shall be open to inspection by any officer authorized by the Programme Officer.

(2) A serially numbered inspection book shall be maintained by the licensee in good condition for the use of such officer.

Transport of controlled substances.

15. (1) No consignment of controlled substance shall be transported, imported in the State, or exported from the State, by any person other than the licensed dealers and authorized persons.

(2) The licensed dealer or the authorized person shall submit a copy of the license issued under the Drugs and Cosmetics Act, 1940 or the Sikkim (Repeal and Miscellaneous Provisions) Act, 1985 or any other permit or authorization issued in respect of the controlled substance by the Programme Officer, or an officer appointed by the Government to act on his behalf to issue the authorization, when the same is demanded by an officer appointed under sub-section (1) of section 21 of the Act.

Maintenance of records.

16. The licensed dealer or the authorized person shall maintain detail records of all such transport of controlled substance and submit a report to the Programme Officer, or an officer appointed by the Government, on a quarterly basis with details of all such transactions in such Form VI appended to these rules.

CHAPTER IV
POSSESSION, USE AND CONSUMPTION OF CONTROLLED SUBSTANCES

Possession of controlled substance.

17. (1) No person shall possess any controlled substance, unless he is lawfully authorized to possess such substance for any of the said provisions in the rules.

(2) Notwithstanding anything contained in sub-rule (1), any person who is not so authorized under clause (c) of rule 2 of the Rules, may possess a quantity of such controlled substance that is

commensurate with his personal need, and shall carry with him the valid prescription of a registered medical practitioner, or hospital, or an institution authorized to prescribe the same, and the quantity of the controlled substance in his possession shall not exceed the quantity so prescribed:

Provided that a person, who is carrying the controlled substance for another person, shall carry with him a valid prescription for such person, and the quantity so possessed shall not exceed the quantity so prescribed.

(3) The provision of sub-rule (1) shall not apply to-

(i) common carriers or warehouseman while engaged in lawfully transporting or storing such substances or to any employee of the same acting within the scope of his employment;

(ii) public officers or the employees in the lawful performance of their official duties requiring possession of controlled substances; or

(iii) temporary incidental possession by employees or agents of persons lawfully entitled to possession or by persons whose possession is for the purpose of aiding public officers in performing their official duties.

Use and consumption of controlled substance.

18. (1) No person shall use or consume any controlled substance unless he is lawfully authorized to do so for any of the said purposes in the rules.

(2) Notwithstanding anything contained in sub-rule (1), a controlled substance may be used for-

(i) therapeutic requirement by a person who has been prescribed the medicine by a registered medical practitioner, a hospital, or an institution for the possible cure of ailment, or amelioration of symptoms.

(ii) scientific requirement including analytical requirements of any Government laboratory or research institution; or

(iii) the purpose of de-addiction of drug addicts by the Government or by an approved charity or by such other institution as may be approved by the government.

Special provision for controlled substances other than prescription drugs.

19. The sale, transport, possession, use or consumption of a controlled substance other than prescription drugs as declared by the Government in the notification made under clause (iii) of section 2 of the Act, shall –

(i) be made only by a dealer with a valid trade license issued under the Sikkim (Repeal and Miscellaneous Provisions) Act, 1985, and who has been further issued with a special permit to carry on the trade of such substances by the Programme Officer or an officer appointed for the purpose by the Government;

(ii) be made only by a dealer who shall keep the record of transactions in a register with details of purchase and sale and issue a memo to the person to whom it is sold, with details of date of sale, name of the person, quantity and other particulars as is relevant to establish the process of transaction;

(iii) not be made without a valid cash memo or bill, issued by the dealer from whom the substance is procured or purchased, and shall show such cash memo or bill, when asked upon;

(iv) not be made without a valid purchase voucher obtained in his name, or firm, or company from the agent, or distributor, or wholesaler, from whom such substance is procured or purchased; and

(v) not be made by any person, or in any place, save the person or place where the use or consumption is a necessity and where it is routinely used or consumed.

FORM I

(See rule 5)

LICENCE FOR MANUFACTURE OF CONTROLLED SUBSTANCES

License No. ..... Date of issue ..... Name of Firm ..... is hereby licensed to manufacture the following controlled substances on the premises situated at .....

	Name of Controlled Substance	Quantity
1.		
2.		
3.		

The licence shall be in force from ..... to .....

The licence is subject to the conditions stated below and to such other conditions as may be specified in the rules for the time being in force under the Sikkim Anti Drugs Act, 2006 (2 0f 2006).

Date .....

Signature

Designation

Conditions of License

1. This license is not transferable.
2. The license or any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of an officer detailed for the purposes by the Programme Officer.
3. The licensee shall not manufacture or keep the controlled substances or the materials used for the manufacture of such substances at any other place except his place of business.
4. The licensee shall, in case of medicinal preparations, ensure manufacture of the drug to the standard and specifications laid down by or under the Drugs and Cosmetics Act, 1940 (23 of 1940).
5. The licensee, if he desires renewal of the licence, shall apply to the Programme Officer, in the form specified, at least thirty days before the expiry of his licence.

FORM II

(See rule 6)

FORM OF APPLICATION FOR GRANT/RENEWAL OF LICENSE FOR MANUFACTURE OF CONTROLLED SUBSTANCES

1. I/We ..... of ..... hereby apply for the grant/renewal of a license to manufacture on the premises situated at ..... the following controlled substances being the substances covered by the Sikkim Anti Drugs Act, 2006.
2. Name of the controlled substances.
3. Names, qualifications and experience of technical staff employed for manufacture and testing.
4. A fee of Rs..... has been credited to the Government under the head of account.

Date .....

Signature

Note: This application should be accompanied by the plan of the premises.

FORM III

(See rule 9)

QUARTERLY RETURN OF MANUFACTURE OF CONTROLLED SUBSTANCES

Return for the quarter ending on .....

1. Name of the manufacturer with license No.
2. Address
3. Name of the controlled substance
4. Opening balance of the controlled substance at the beginning of the quarter
5. Details of the manufacture and sale

Manufacture:

Sale:

6. Name, address, license No. and location of the premises of the person to whom sold
7. Closing balance at the end of the quarter.

Certified that the information given above is correct and the relevant records are available with me/us.

Date ..... **Signature**

Name

Designation

Note:

1. The quantity should be indicated in the number of units.
2. For each controlled substance, separate return shall be sent.
3. This return is to be sent to the Programme Officer designated under the Act.

FORM IV

(See rule 13)

REGISTER FOR CONSUMPTION AND SALE OF CONTROLLED SUBSTANCES

Date: Name of Controlled Substance

1. Quantity at hand at the beginning of day

2. Details of quantity of the substance received
   (a) Quantity received
   (b) From whom received (name, address of the person/firm with the Drugs license/ TradeLicense/Authorisation number
   (c) Bill No. and date

3. Details of the substances distributed/sold
   (a) Quantity sold/distributed
   (b) To whom sold/sent/distributed (name, address of the person/firm with name of doctor/ institution or Drugs license/Trade License of the firm)

4. Quantity at hand at the close of day

Note:

1. The quantity shall be indicated in number of units.

2. This record shall be maintained on day-to-day basis and entries shall be made for each day the establishment opens for work irrespective of whether there are any transactions or not and the entries shall be completed for each day before the close of the day and the in-charge of the establishment shall initial after the entries are made. The pages of the register shall contain running number.

3. If more than one controlled substance is dealt with, separate register shall be maintained for each such substance.

FORM V

(See rule 13)

QUARTERLY REPORT OF RECEIPT, IMPORT, SALE OR CONSUMPTION OF CONTROLLED SUBSTANCE

Return for the quarter ending on .....

1. Name of the seller/distributor/importer
2. Address with license/Authorisation number
3. Name of the controlled substance
4. Opening balance at the beginning of the quarter
5. Details of quantity received and sold or consumed

Receipt

1. Date
2. Received from whom (name, address and license no.)
3. Bill No.
4. Quantity received

Total

Sale or consumption

1. Date
2. To whom sold Name, address and prescription by doctor/institution)
3. Cash Memo No.
4. Quantity sold or consumed

Total

5. Closing balance at the end of the quarter

Certified that the information given above is correct and the relevant records re available with me/us.

Date.....

Signature

Name

Designation

1. The quantity should be indicated in number of units.
2. Foe each controlled substance, separate return shall be sent.
3. This return should be sent to the Programme Officer designated under the Act.

FORM VI

(See rule 16)

QUARTERLY REPORT ON TRANSPORT OF CONTROLLED SUBSTANCES

Report for the quarter ending on .....

1. Name of the consignor
2. Address
3. Name of the controlled substance
4. Details of the consignment sent

1. Date on which sent
2. Quantity
3. To whom sent (name, address)
4. Consignment note/Bill No.
5. Mode of transportation

Date .....

Signature

Name

Designation

Note:

1. The quantity shall be indicated in the number of units.
2. For each controlled substance, a separate return shall be sent.
3. This report is to be sent to the Programme Officer designated under the Act.

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